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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,571	06/05/2008	Lisa C. Kadyk	EX03-089C-US	8822

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EXAMINER	
CHEU, CHANGHWA J	

ART UNIT	PAPER NUMBER
1641	

MAIL DATE	DELIVERY MODE
12/03/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/535,571	KADYK ET AL.	
	Examiner	Art Unit	
	JACOB CHEU	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 October 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *23-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/2/2005, 6/5/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Election/Restrictions

1. Applicant's election with traverse of group I, claims 1-22 in the reply filed on 10/18/2010 is acknowledged.

2. Applicant pointed out that the MacDonald et al. reference using MINK gene instead of MAPK. Applicant's arguments have been considered, but are not persuasive. However, MAPK gene is in fact disclosed in the MacDonald et al. reference (See Abstract and Title).

3. Currently claims 1-25 are pending and claims 23-25 are withdrawn from further examination.

4. Claims 1-22 are under examination.

Claim Rejections - 35 USC § 112

enablement

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As set forth in *In re Wands, 858 F .2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988)*, enablement requires that the specification teach those skilled in the art to make and use the invention without undue experimentation. Factors to be considered in determining, whether a disclosure would require undue experimentation include 1) the nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the quantity of experimentation necessary, 7) the relative skill of those in the art, and 8) the breadth of the claims.

It is noted that the current invention uses genetic screening designed to identify modifiers of the Rac, axin and beta-catenin pathway. The basic technique is using the mutant and wild type of C.elegans. where genetic alternations on Rac, axin and beta-catenin genes have been conferred to the mutant worms and compared to the phenotype of functionality, e.g. cellular migration, vulva formation and cellular adhesion (See Examples; section 0117-0129, PG-Publication).

Applicant identified ZC504.4 in all three genetic screening. Applicant states:

IV. Sequence Analysis

[0130]BLAST analysis (Altschul et al., supra) was employed to identify orthologs of C. elegans ZC504.4. For example, representative sequences from MAPK, SEQ ID NOs:36, 37, and 38 share **45%, 48%, and 45%** amino acid identity, respectively, with the C. elegans ZC504 (emphasis added; Section 0130, PG-Publication).

The "extrapolation" herein on the modifiers over Rac, axin and beta-catenin pathways are merely based on the 45%, 48% and 45%, respectively, homology as shown above.

With such limited information, absence of identified conserved region(s) of interaction between the Rac, axin and beta-catenin, human MAPK, one ordinary skill in the art would not jump to conclusion that any compound capable of modulating this ZC504.4 is definitely involving in the Rac, axin and beta-catenin pathways since more experiments are needed to design and conduct to further verify this conclusion. It is also reasonably conceivable that some compounds (capable of modulating ZC504.4) which fall **outside** the homology range, i.e. another 50% diversity (not homologous with MAPK), will be falsely identified as the potential modifiers (emphasis added). Taken together, with the insufficient disclosure to thisZC504.4, it would inevitably impose

undue experiments to one ordinary skill in the art to further verify whether the identified compounds are in fact associated with RAC pathway.

Claim Rejections - 35 USC § 112

Written Description

1. Claims 1-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by the inventor. *Vas-Cath Inc. v. Mahurkar,* 935 F.2d 1555, 1563 (Fed. Cir. 1991). The inventor can demonstrate possession by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention.

An inventor needs to show that the inventor was "in possession" of the invention by describing the invention, with all its claimed limitations, not that which makes it obvious. *Lockwood v. American Airlines, Inc.,*

107 F.3d 1565, 1571-72 (Fed. Cir. 1997). Requiring possession of the invention, and not that which makes it obvious, ensures that the claimed invention does not overreach the scope of the inventor's contribution to the field as described in the patent specification. *Reiffin v. Microsoft Corp.,* 214 F.3d 1342, 1345 (Fed. Cir. 2000). Depending on the facts of the case, description of a chemical genus can require something more than the description of a single

species but less than all species encompassed by the claimed genus. *Cf., Regent of the Univ. of Cal. v. Eli Lilly & Co.,* 119 F.3d 1559, 1568 (Fed. Cir. 1997). As held in *Brenner v. Manson*, "[a] patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." See 383 U.S. 519, 536 (1966).

The newly released "written description training guidelines" from this Office has a similar example illustrating the lack of written description in a claimed protein or fragment with functional activity (See claim 2 of Example 11A Percent Identity; http://www.uspto.gov/web/menu/written.pdf). In this example given by the Office, claim 2, "*an isolated nucleotide encoding the polypeptide with at least 85% sequence identity to SEQ ID No. 2, wherein the polypeptide has activity X*", is rejected mainly due to lack of disclosure on the correlation of structure and function on the protein. As discussed above, Applicant merely discloses a **less than 50 % homology** peptide to MAPK (emphasis added). Similarly, there is no disclosure to the correlation of the function with any conserved domain(s) or region(s) on this peptide. In addition, no teaching or suggestion is revealed on the variations of deletion or addition on the protein that can be tolerated without losing the functional characteristics. Moreover, thus far Applicant merely shows ONE species ZC504.4 (with less than 50% homology) for this MAPK genus. It appears lacking a representative number of species justifying possession of whole genus. As in *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, the court clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification needs "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. One cannot describe what one has not conceived.

2. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JACOB CHEU whose telephone number is (571)272-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jacob Cheu/
Primary Examiner, Art Unit 1641

3.